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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,076

12/02/2003

Mark Zoller

67824.713001

2702

21967 7590 04/29/2009

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

04/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,076	Applicant(s) ZOLLER ET AL.	
	Examiner Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 194-252 is/are pending in the application.
- 4a) Of the above claim(s) 216 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 194-215 and 217-252 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/24/09 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/23/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

A. Applicant's election without traverse of Group I, claims 194-215 and 217-252 in the reply filed on 3/24/09 is acknowledged. Claim 216 is withdrawn as being drawn to a non-elected invention (SEQ ID NO:4).

2. Specification

A. Though none could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

B. Though none could be found, trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

C. Though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.

3. Claim Objections

- A. Claim 194 is objected to since the term "receptor associated" should be hyphenated.
- B. The syntax of claim 194 would be clearer if part (ii)(b) was amended to recite "specific binding of said another compound"
- C. At least claims 198-215 and 217 should be amended to recite "of" instead of "contained in". As written, the T1R receptor could has as few as one amino acid, since this would be "contained in" SEQ ID NO:6, for example.
- D. Claim 207 is objected to since it recites "is a polypeptide is a fragment".

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- E. Claim 207 is also objected to since it recites “points to”.
- F. Claim 208 recites “compounded a fragment”. This is unclear.
- G. Claim 219 should recite “is expressed”.
- H. In claim 220 the phrase “comprised in a membrane extract” should be amended (e.g. “present in”).
- I. In claim 223 the phrase “comprised in a liquid bilayer” should be amended 9e.g. “present in”). Furthermore, it is believed the claim should recite “**lipid** bilayer”.
- J. In claim 237 the term “solid receptor” is unclear.
- K. In claim 241 the phrase of “wherein to binding assay” should be amended.
- L. In claims 242 and 243 it appears that the phrase “effect of said compound on the” should be removed.
- M. In claim 244 the phrase “assay under a cell” is unclear.
- N. In claim 245 the term “which” should be replaced with “wherein”.
- O. In claim 249 the term “high-throughput” should be hyphenated.
- P. Claim 252 recites “(3)”. However, there is no “(1)” and “(2)” in the claim from which it depends.

4. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- A. Claims 206, 210 and 217 are vague and indefinite since the claim recites “stringent conditions.” It is not known what these conditions are. Nucleic acid molecules which hybridize under conditions of “low” stringency would not necessarily hybridize under conditions of “high” stringency. Furthermore, not all conditions of “high” or “low” stringency, for example, are the same. Therefore, it is required that Applicants amend the claims to recite the exact hybridization conditions without using indefinite phrases such as “*for example*” **without adding new matter**.
- B. At least claims 198-215 and 217 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase “contained in” is unclear. It is not understood if the claim refers to

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the full-length of the claimed SEQ ID NO, or a fragment thereof which encodes the functional receptor, for which the specification has not described.

5. Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 194-197 and 219-252 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zuker et al. (U.S. Patent No. 7,402,400). The instant claims recite methods of screening for modulators of T1R2/T1R3 heteromers of various species using various expression systems (e.g. membrane extract) and assay conditions. Zuker et al. teach

These screening methods and assay systems column 1, lines 35-40 (T1R2/T1R3 heteromer); column 4, line 30 to line 61 (assay systems); column 9, lines 28-64 (assay systems) and column 10, lines 48 to column 11, line 9 (compounds). Any specific claim limitation not taught by Zuker would have been obvious to one of ordinary skill in the art at the time of the instant invention based on the teachings of Zuker since screening assays for G protein-coupled receptors. Minor differences in assay conditions or cell preparation were common at the time.

6. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 194-215 and 217-252 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-114 of U.S. Patent **6,955,887** (09/897,427), claims 1-37 of U.S. Patent No. **7,297,772** (10/725,037); claims 1-65 U.S. Patent No. **7,297,543** (10/725,103), claims 1-41 of U.S. Patent No. **7,344,859** (10/725,472) and claims 1-66 of U.S. Patent **7,294,474** (10/725,475). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application recites a methods of screening using a T1R2/T1R3 dimers, including those of SEQ ID NO:6 and 7. The '887 patent recites methods of screening T1R2/T1R3 receptors. The '772 patent recites the heteromeric taste receptors themselves. The '543 patent recites a recombinant cell comprising this dimer. The '859 patent recites a method of expressing the dimer and the '474 patent also recites screening T1R2/T1R3 receptors, including those of SEQ ID NO:6 and 7. Methods of making and using the dimer are obvious over the recombinant cells.

B. Claims 194-215 and 217-252 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 100-193 of copending Application No. **12/185,392**, claims 44-88 of copending Application No. **11/932,949**, claims 44-88 of copending application **11/932,493**, claims 303-328 of copending application **11/797,156**, claims 68-96 of copending application **11/583,097**, claims 23 and 24 of copending application **10/569,870** and claims 21, 27, 28, 29 and 31 of copending application **11/395,375**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to methods of screening modulators of a T1R2/T1R3 heteromer, including using receptors which hybridize SEQ ID NO:9 or 10, or are homologous to SEQ ID NO:6 and 7. The instant claims also recite various expression and assay systems. The '392 application also teaches screening methods using T1R2/T1R3 heteromers, including those which hybridize, or are homologous to various taste receptors, or their encoding polynucleotides. The '392 application also teaches various expression and assay systems as recited in the instant claims. The '949 application teaches methods of screening T1R2/T1R3 heteromers, as well as various expression and assay systems recited in the instant claims. The '493 application recites identical claims as '392. The

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'156 application recites nucleic acid molecules expressing various T1R2/T1R3 heteromers which hybridize to the claimed sequences as well as cells expressing these heteromers. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the cells expressing these T1R2/T1R3 heteromers to screen for ligands which modulate its function. This method is disclosed on at least page 6, lines 14-18 of the '156 specification. The '097 application recites chimeric receptors comprising T1R2 and another T1R receptor (or those 90% identical to the transmembrane or extracellular region). The T1R3 receptor of the instant invention would meet these limitations. The '870 application recites heteromeric T1R2/T1R3 receptors (those 909% identical to native rat or human sequences). Finally, the '375 application recites methods of screening agonists of T1R2/T1R3 heteromers (95% identity to endogenous receptors).

In applications which do not recite generic T1R2/T1R3 heteromers (i.e. if all claims are drawn to specific SEQ ID NOs), if it would not be expected that the polynucleotides of the copending applications would not hybridize to those of the instant application, or vice versa, or the T1R2 and T1R3 polypeptides would not meet the homology limitations, Applicants are urged to provide arguments or evidence of such.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647